

Applicants : Michael Wayne Graham and Robert Norman Rice  
Serial No. : 10/759,841  
Filed : January 15, 2004  
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#### **REMARKS**

Claims 172, 176-179, 181-188, 190-193, 195-197, 199-200, 202-205, 207-209 and 211-244 were pending in the subject application. Applicants have amended claims 172, 188, and 200 to recite the limitations of allowable claims 212-214, respectively, amended claims 188, 199, 200, and 211 to delete the recitation of "construct," and canceled claims 187 and 212-244 without disclaimer or prejudice as to Applicants' right to pursue the subject matter of these claims in the future. Support for the amendments to the claims can be found, *inter alia*, in the specification as filed at page 2, lines 28-30 and page 10, lines 15-17.

Accordingly, amended claims 172, 176-179, 181-186, 188, 190-193, 195-197, 199-200, 202-205, 207-209 and 211 are pending in the subject application, and should be allowed because the claims recite subject matter indicated as allowable in the March 9, 2010 Office Action.

#### **Summary of April 8, 2010 Examiner Interview**

On April 8, 2010 a telephonic Examiner Interview was conducted in connection with the subject application. Present during the interview were Examiner Brian Whiteman, Supervisory Patent Examiner Fereydoun Sajjadi, Quality Assurance Officer Bennett Celsa, Robert de Feyter, Bill Pickering, Sue MacLeman, James Cherry, and the undersigned. Applicants are submitting this Summary pursuant to 37 C.F.R. § 1.133(b) to supplement the April 15, 2010 Interview Summary issued by the United States Patent and Trademark Office in connection with the subject application. Applicants acknowledge with appreciation the courtesy that Examiner Whiteman, Supervisory Patent Examiner Sajjadi and

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Quality Assurance Officer Celsa extended during the April 8, 2010  
interview.

Applicants requested the April 8, 2010 interview to discuss the  
asserted grounds of rejection set forth in the March 9, 2010  
Office Action issued in connection with the subject application.  
Claims 172, 176, 180, 181, 184, 185, 187, 188, 190, 195, 199,  
200, 202, 207, and 211-244 were discussed. Applicants presented  
reasons warranting a finding of patentability of the then pending  
claims. The Examiners indicated that they will consider the  
reasons upon submission of Applicants' written response.

#### **Information Disclosure Statement**

On page 2 of the March 9, 2010 Office Action, the Examiner stated  
that the plasmid map for pCR2.1, submitted in a Supplemental  
Information Disclosure Statement received by the USPTO on  
September 28, 2009, and the Third Party Observations under  
article 115 EPC against European Patent Application EP 98964202.0  
in the name of Carnegie Institution of Washington, submitted in a  
Supplemental Information Disclosure Statement received by the  
USPTO on October 2, 2009, have not been considered because there  
is no date listed for either the plasmid map or Third Party  
Observations.

In response, Applicants list the plasmid map for pCR2.1,  
submitted July 11, 2008 in connection with Merged Reexamination  
Nos. 90/007,247 and 90/008,096, filed October 4, 2004 and May 18,  
2006, respectively, and the Third Party Observations under  
article 115 EPC against European Patent Application EP 98964202.0  
in the name of Carnegie Institution of Washington, submitted to  
the European Patent Office on March 24, 2009, as items 1 and 2,  
respectively, of the Supplemental Information Disclosure

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Statement submitted herewith. The date of submission of the  
plasmid map of pCR2.1 to the USPTO and the date of submission of  
the Third Party Observations to the European Patent Office are  
listed on the accompanying Form PTO-1449 (Substitute) in  
accordance with the provisions of 37 C.F.R. §§ 1.97-1.98 and  
M.P.E.P. § 609.

**Claim Rejections Under 35 U.S.C. § 112, first paragraph, written  
description**

The March 9, 2010 Office Action rejected claims 215-244 under 35  
U.S.C. § 112, first paragraph, as allegedly failing to comply  
with the written description requirement. The Examiner's  
specific rationale is set forth on pages 3 through 5 of the March  
9, 2009 Office Action.

**Applicants' Response**

In response, to expedite prosecution but without conceding the  
correctness of this rejection, Applicants have amended the claims  
to cancel claims 215-244. Accordingly, this rejection is now  
moot.

**Claim Rejections Under 35 § 103(a) - Fire et al. Patent taken  
with Cowsert et al.**

The March 9, 2010 Office Action rejected claims 172, 176, 180,  
181, 184, 185, 187, 188, 190, 195, 199, 200, 202, 207, 211, 214-  
219, 222, 223, 225-230, 233-238, and 241 under 35 U.S.C. § 103(a)  
as allegedly unpatentable over Fire et al. (U.S. Patent No.  
6,506,559) taken with Cowsert et al. (U.S. Patent No. 5,580,767).  
The Examiner's specific rationale is set forth on pages 7 through  
20 of the March 9, 2009 Office Action.

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**Applicants' Response**

In response, to expedite prosecution but without conceding the correctness of this rejection, Applicants have amended independent claims 172, 188, and 200 to recite the limitations of allowable claims 212-214, respectively. Claims 212-214 were objected to as being dependent upon a rejected base claim, i.e. claims 172, 188, and 200, respectively, but indicated as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Accordingly, Applicants believe the claims as amended herein are in condition for allowance and respectfully request reconsideration and withdrawal of this rejection.

**Claim Rejections Under 35 § 103(a) - Agrawal et al. in view of Kool and Cowsert et al.**

The March 9, 2010 Office Action rejected claims 172, 176-179, 181, 184-188, 190-193, 195, 199, 200, 202-205, 207, and 211 under 35 U.S.C. § 103(a) as allegedly unpatentable over Agrawal et al. (WO 94/01550) in view of Kool (U.S. Patent No. 5,514,546) and Cowsert et al. (U.S. Patent No. 5,580,767). The Examiner's specific rationale is set forth on pages 20 through 24 of the March 9, 2010 Office Action.

**Applicants' Response**

In response, to expedite prosecution but without conceding the correctness of this rejection, Applicants have amended independent claims 172, 188, and 200 to recite the limitations of allowable claims 212-214, respectively. Claims 212-214 were objected to as being dependent upon a rejected base claim, i.e. claims 172, 188, and 200, respectively, but indicated as

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allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Accordingly, Applicants believe the claims as amended herein are in condition for allowance and respectfully request reconsideration and withdrawal of this rejection.

**Claim Rejections Under 35 § 103(a) - Fire et al. Patent taken with Cowsert et al. in further view of Agrawal et al.**

The March 9, 2010 Office Action rejected claims 172, 177-179, 188, 191-193, 200, and 203-205 under 35 U.S.C. § 103(a) as allegedly unpatentable over Fire et al. taken with Cowsert et al. as applied to claims 172, 176, 180, 181, 184, 185, 187, 188, 190, 195, 199, 200, 202, 207, 211, 214-219, 222, 223, 225-230, 233-238, and 241, and further in view of Agrawal et al. The Examiner's specific rationale is set forth on pages 25 through 26 of the March 9, 2009 Office Action.

***Applicants' Response***

In response, to expedite prosecution but without conceding the correctness of this rejection, Applicants have amended independent claims 172, 188, and 200 to recite the limitations of allowable claims 212-214, respectively. Claims 212-214 were objected to as being dependent upon a rejected base claim, i.e. claims 172, 188, and 200, respectively, but indicated as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Accordingly, Applicants believe the claims as amended herein are in condition for allowance and respectfully request reconsideration and withdrawal of this rejection.

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**Claim Rejections Under 35 § 103(a) - Fire et al. Patent taken  
with Cowsert et al. in further view of Kool**

The March 9, 2010 Office Action rejected claims 172, 186, 215, and 224 under 35 U.S.C. § 103(a) as allegedly unpatentable over Fire et al. taken with Cowsert et al. as applied to claims 172, 176, 180, 181, 184, 185, 187, 188, 190, 195, 199, 200, 202, 207, 211, 214-219, 222, 223, 225-230, 233-238, and 241, and further in view of Kool. The Examiner's specific rationale is set forth on pages 26 through 27 of the March 9, 2009 Office Action.

***Applicants' Response***

In response, to expedite prosecution but without conceding the correctness of this rejection, Applicants have amended independent claims 172, 188, and 200 to recite the limitations of allowable claims 212-214, respectively. Claims 212-214 were objected to as being dependent upon a rejected base claim, i.e. claims 172, 188, and 200, respectively, but indicated as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Accordingly, Applicants believe the claims as amended herein are in condition for allowance and respectfully request reconsideration and withdrawal of this rejection.

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants direct the Examiner's attention to the following references which are listed on the Form PTO-1449 (Substitute) attached hereto as **Exhibit A**.

Items 1-60 listed below have been submitted to or provided by the United States Patent and Trademark Office in related patent applications. Applicants attach hereto as **Exhibit B** a table listing locations where a copy of each listed reference may be found. Applicants respectfully direct the Examiner to the Image File Wrapper of the appropriate related application for a copy of the reference.

According to 37 C.F.R. § 1.97(c), a Supplemental Information Disclosure Statement filed after the period specified in 37 C.F.R. § 1.97(b) shall be considered if accompanied by the fee set forth in 37 C.F.R. § 1.17(p) or a statement under 37 C.F.R. § 1.97(e). The required fee set forth in 37 C.F.R. § 1.17(p) is one hundred eighty dollars (\$180.00) and a check including this amount is enclosed. Accordingly, this Supplemental Information Statement shall be considered.

The Examiner is respectfully requested to make these references of record in the above-identified application by initialing and returning a copy of the enclosed Form PTO-1449 (Substitute).

1. Plasmid map for pCR2.1, submitted July 11, 2008 in connection with Merged Reexamination Nos. 90/007,247 and 90/008,096, filed October 4, 2004 and May 18, 2006, respectively;

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2. Third Party Observations under article 115 EPC against European Patent Application EP 98964202.0 in the name of Carnegie Institution of Washington, submitted to the European Patent Office on March 24, 2009;
3. Supplemental Amendment To October 15, 2009 Amendment Filed In Response To May 15, 2009 Final Office Action, Summary of Examiner Interviews, And Supplemental Information Disclosure Statement submitted December 21, 2009 in connection with U.S. Serial No. 10/346,853, filed January 17, 2003;
4. Amendment in Response to May 15, 2009 Final Office Action as a Submission to Accompanying Request for Continued Examination submitted October 15, 2009 in connection with U.S. Serial No. 10/346,853, filed January 17, 2003;
5. Office Action issued April 15, 2010 in connection with U.S. Serial No. 10/346,853, filed January 7, 2003;
6. Office Action issued March 9, 2010 in connection with U.S. Serial No. 10/821,726, filed April 8, 2004;
7. Terminal Disclaimer submitted November 11, 2009 in connection with U.S. Serial NO. 10/646,070, filed July 13, 2005;
8. Terminal Disclaimer submitted December 14, 2009 in connection with U.S. Serial NO. 10/646,070, filed July 13, 2005;
9. Notice of Allowability issued January 27, 2010 in connection with U.S. Serial No. 10/646,070, filed August 22, 2003;
10. Supplemental Information Disclosure Statement submitted April 27, 2010 in connection with U.S. Serial No. 10/646,070, filed August 22, 2003;



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11. Office Action issued October 9, 2009 in connection with U.S. Serial No. 11/218,999, filed September 2, 2005;
12. Amendment in Response to October 9, 2009 Final Office Action as a Submission to Accompanying Request for Continued Examination submitted March 9, 2010 in connection with U.S. Serial No. 11/218,999, filed September 2, 2005;
13. Office Action issued April 21, 2010 in connection with U.S. Serial No. 11/218,999, filed September 2, 2005;
14. Examiner's Answer issued January 7, 2010 in response to applicant's Appeal Brief filed 7/27/09 in connection with Merged Reexamination Nos. 90/007,247 and 90/008,096, filed October 4, 2004 and May 18, 2006, respectively;
15. Reply Brief to Examiner's Answer submitted on 3/8/10, in connection with merged Reexamination Control Nos. 90/007,247 and 90/008,096, filed October 4, 2004 and May 18, 2006, respectively;
16. Request for Oral Hearing submitted 3/8/10, in connection with merged Reexamination Control Nos. 90/007,247 and 90/008,096, filed October 4, 2004 and May 18, 2006, respectively;
17. Office Action issued December 8, 2009 in connection with U.S. Serial No. 09/287,632, filed April 7, 1999;
18. Appeal Brief submitted April 8, 2010 in connection with U.S. Serial No. 09/287,632, filed April 7, 1999 ;
19. Revised Amendment and Reply submitted August 10, 2009 in connection with U.S. Serial No. 11/364,183, filed March 1, 2006;

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20. Reply to the November 4, 2009 Office Action submitted May 4, 2010 in connection with U.S. Serial No. 11/364,183, filed March 1, 2006;
21. Amendment submitted February 12, 2010 in connection with U.S. Serial No. 11/841,737, filed August 20, 2007;
22. Final Rejection issued April 23, 2010 in connection with U.S. Serial No. 11/841,737, filed August 20, 2007;
23. U.S. Serial No. 12/798,247, filed March 31, 2010 (Waterhouse et al.);
24. U.S. Patent Publication No. 2005/0095199 A1, published May 5, 2005 (U.S. Serial No. 10/482,888, filed June 14, 2004; Steven Whyard et al.), including complete file history;
25. Office Action issued September 12, 2008 in connection with U.S. Serial No. 11/593,056, filed November 6, 2006;
26. Amendment submitted March 12, 2009 in connection with U.S. Serial No. 11/593,056, filed November 6, 2006;
27. Office Action issued June 24, 2009 in connection with U.S. Serial No. 11/593,056, filed November 6, 2006;
28. Amendment submitted December 23, 2009 in connection with U.S. Serial No. 11/593,056, filed November 6, 2006;
29. Final Office Action issued March 24, 2010 in connection with U.S. Serial No. 11/593,056, filed November 6, 2006;
30. Response submitted February 3, 2010 in connection with U.S. Serial No. 11/179,504, filed July 13, 2005;
31. Advisory Action issued February 16, 2010 in connection with U.S. Serial No. 11/179,504, filed July 13, 2005;
32. Amendment as a Submission to Accompanying Request for Continued Examination submitted April 19, 2010 in

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connection with U.S. Serial No. 11/179,504, filed July  
13, 2005;

33. Office Action issued August 28, 2009 in connection with  
Canadian Patent Application No. 2455490, issued by the  
Canadian Intellectual Property Office;
34. Declaration of David M. Stalker filed in opposition to  
Australian Patent Application No. 778474 (November 4,  
2008);
35. Reply Brief to Examiner's Answer filed on 8/26/09,  
application no. 10/805,804;
36. Appeal Brief filed on 3/6/09 in Application No.  
10/805,804;
37. Wolff et al. (1995) "Mutational analysis of human U6 RNA:  
stabilizing the intramolecular helix blocks the  
spliceosomal assembly pathway," Biochim. Biophys. Acta  
1263: 39-44;
38. Image of U6 snoRNA secondary structure retrieved from  
[http://gene.fudan.sh.cn/snoRNASecStruct/Box%20C&D/Homo%20sapiens/U16\\_ss\\_p0001.jpg](http://gene.fudan.sh.cn/snoRNASecStruct/Box%20C&D/Homo%20sapiens/U16_ss_p0001.jpg) on 9/17/09;
39. Allen et al. (2007) "Development of strategies for  
conditional RNA interference," J. Gene Med. 9: 287-298;
40. U.S. Patent No. 5,413,906 (Eberle et al.), May 9, 1995
41. U.S. Patent No. 5,602,242 (Ahlquist et al.), February 11,  
1997;
42. Wharton et al. (1994) Journal of General Virology,  
75:945-948;
43. Supplementary European Search Report issued February 12,  
2010 in connection with European Patent Application No.  
04761272;

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44. European Patent Application No. 0784094 A1, published July 16, 1997;
45. European Patent Application No. 0779365 A2, published June 18, 1997;
46. PCT International Publication No. WO 98/50408 A1, published November 12, 1998;
47. PCT International Publication No. WO 03/095647 A2, published November 20, 2003;
48. Beck, J., et al. (1995), "Efficient hammerhead ribozyme-mediated cleavage of the structured hepatitis B virus encapsidation signal in vitro and in cell extracts, but not in intact cells," Nucleic Acids Research, vol. 23, no. 24: 4954-4962;
49. De Angelis, F.G., et al. (2002), "Chimeric snRNA molecules carrying antisense sequences against the splice junctions of exon 51 of the dystrophin pre-mRNA induce exon skipping and restoration of a dystrophin synthesis in delta 48-50 DMD cells," PNAS, vol. 99, no. 14: 9456-9461;
50. Suter, D., et al. (1999), "Double-target antisense U7 snRNAs promote efficient skipping of an aberrant exon in three human beta-thalassemic mutations," Human Molecular Genetics, vol. 8: 2415-2423;
51. Baulcomb (1996), "Mechanisms of Pathogen-Derived Resistance to Viruses in Transgenic Plants," Plant Cell, vol 8:1833-1844;
52. U.S. Patent No. 6,451,603 (Atkins et al.), September 17, 2002;

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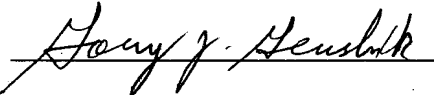
53. Nobelprize.org: The Nobel Prize in Physiology or Medicine  
2006, Press Release of the Nobel Assembly at Karolinska  
Institute (October 2, 2006);
54. Genbank Accession No. L26296, June 28, 1994;
55. Genbank Accession No. AF 124360, July 21, 2000;
56. Genbank Accession No. A65102, November 14, 2006;
57. Genbank Accession No. AF043841, June 5, 1999;
58. U.S. Patent No. 6,919,466 (Lightner et al.), July 19,  
2005;
59. U.S. Published Application No. 2002/0166144 (Green et  
al.), November 7, 2002;
60. Doelling et al. (1995), PNAS Vol 8:683-692; and
61. Office Communication issued June 8, 2010 in connection  
with U.S. Serial No. 11/364,183, filed March 1, 2006.

If a telephone interview would be of assistance in advancing  
prosecution of the subject application, Applicants' undersigned  
attorney invites the Examiner to telephone him at the number  
provided below.

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No fee, other than the enclosed total fee of \$310.00 (\$130.00 fee for a one-month extension of time and \$180.00 fee for filing a Supplemental Information Disclosure Statement), is deemed necessary in connection with the filing of this Amendment, Examiner Interview Summary and Supplemental Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Gary J. Gershik Date  
Reg. No. 39,992

# **EXHIBIT A**